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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/857,669

09/21/2001

Jean-Louis Ruelle

BM45339

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25308

7590

12/18/2002

DECHERT

ATTN: ALLEN BLOOM, ESQ  
4000 BELL ATLANTIC TOWER  
1717 ARCH STREET  
PHILADELPHIA, PA 19103

EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/18/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/857,669

Applicant(s)

RUELLE, JEAN-LOUIS

Examiner

Padmavathi v Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 55-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____    | 6) <input type="checkbox"/> Other: _____                                    |

## Interview Summary

Application No.

09/857,669

Applicant(s)

RUELLE, JEAN-LOUIS

Examiner

Padmavathi v Baskar

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1645

All participants (applicant, applicant's representative, PTO personnel):

(1) Padmavathi v Baskar.

(3)\_\_\_\_\_.

(2) Teresa O Bittenbender.

(4)\_\_\_\_\_.

Date of Interview: 04 November 2002 .

Type: a)☒ Telephonic b)☐ Video Conference  
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.

If Yes, brief description: \_\_\_\_\_ .

Claim(s) discussed: 55-62 .

Identification of prior art discussed: \_\_\_\_\_ .

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Attorney of record elected SEQ.ID.NO: 2 for examination of claims 55-62 .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☒ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
Examiner's signature, if required

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### **DETAILED ACTION**

1. Applicant's response to restriction in Paper No. 7 (10/25/02) and interview summary of record 11/4/02, paper # 8 are acknowledged. Claims 28-54 have been canceled and new claims 55-62 have been added and are pending in the application.

#### ***Election***

2. Applicant's election Group I, claims 55-62 with respect to SEQID.NO: 2 without traverse in Paper # 7 and 8 is acknowledged.

#### ***Priority***

3. This application 371 is a national stage entry of PCT/EP99/09560 12/02/1999 which claims priority under 35, U.S.C. 119 (a)- (d) to UNITED KINGDOM 9826886.5 12/07/1998 is acknowledged. Claims 55-62 with respect SEQ.ID.NO: 2 is accorded priority as of 12/7/1998

#### ***Drawings***

4. The drawings are objected to by the draftsperson under 37 C.F.R. 1.84 or 1.152. See PTO-948 for details.

#### ***Information Disclosure Statement***

5. The Information Disclosure Statement has not been filed in this application.

#### ***Specification - Informalities***

6. Applicant should follow the direction or order or arrangement in framing the specification as provided in 37 CFR 1.77(b) since this is a utility application filed in USA. The specification should include all the sections in order. For example: Claims should begin with "I claim" or "we claim" or "What is claimed is".

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It is noted that Abstract of the Disclosure is missing. If applicant desires to include the abstract from PCT/EP99/09560 12/02/1999, a copy of the abstract will be inserted in to the specification. There are no line numbers in the specification pages.

No Brief Description of Drawings are present in the application.

***Claim Rejections - 35 USC 112, second paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
8. Claims 55-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 is rejected as being vague and indefinite for the recitation of "matching----." As written it is impossible to understand whether applicant is claiming an isolated polypeptide comprising from the group consisting of an amino acid sequence that matches with the complete sequence as recited in the SEQ.ID.NO: 2 or something less ?

Claim 62 is rejected for the recitation of " one other M.catarrhalis antigen" since the invention is related to N.meningitidis. It is difficult to understand the metes and bounds of one other antigen as written.

Claim 62 recites the limitations " vaccine " in line 1. There is insufficient antecedent basis for these limitations in the claim.

Applicant is advised to amend the claims to recite only SEQ.ID.NO: 2 since this is an elected invention.

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***Claim Rejections - 35 USC 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims <sup>55-62</sup>~~55-62~~ are rejected under 35 U.S.C. 102(a) as being anticipated by Martin et al 1997 (J.Ex.Med. Volume 185, Number 7, April 7, 1997 1173-1184).

Claims are directed to an isolated polypeptide comprising an amino acid sequence matching amino acid sequence SEQ.ID.NO: 2, a fragment sequence of at least 15 or 20 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2. Claims 61-62 are directed to a immunogenic composition comprising an isolated polypeptide comprising an amino acid sequence matching an amino acid sequence SEQ.ID.NO: 2, a fragment sequence of at least 15 or 20 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2 and one other N.meningitidis antigen (examiner is reading the claim to recite N.meningitidis since the invention is drawn to N.meningitidis) and a pharmaceutically acceptable carrier.

Martin et al disclose an isolated polypeptide, outer membrane protein from whole cell lysate of OM preparations from various clinical isolates including nine meningococcal strains two of serogroup A (604A and Z4063), one of serogroup B (608B [B: 2a:P1.2: L3]), two of serogroup C (2241C and 59C), one of serogroup 29-E, one of serogroup W-135, one of serogroup Y (SLATY) and one of serogroup Z (SLATZ) (page 1174, under materials and method, antigens). Monoclonal antibodies were produced by immunizing mice with OM preparation indicating that the disclosed isolated polypeptides are immunogenic. Therefore, the examiner is considering this preparation as an immunogenic composition. Applicant's use of

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the open-ended term "comprising" in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Whole cell lysates prepared in buffer (pharmaceutical carrier) from *N.meningitidis* inherently comprise the amino acid sequence as set forth in the SEQ.ID.NO: 2 and several *N.meningitidis* antigens. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art protein and the claimed isolated polypeptide comprising SEQ.ID.NO: 2 are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated polypeptide comprising SEQ.ID.NO: 2, with the polypeptide of prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art.

#### Status of Claims

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

12/8/02

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600